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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,306	12/31/2001	Simon M. Furnish	InFraReDx-12	4514
26161	7590	01/03/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			JUNG, WILLIAM C	
			ART UNIT	PAPER NUMBER
			3737	
DATE MAILED: 01/03/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/037,306	FURNISH, SIMON M.	
	<b>Examiner</b>	<b>Art Unit</b>	
	William Jung	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-44 and 46-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 13-25, 30-37, 39-44, and 46-48 is/are rejected.
- 7) ☒ Claim(s) 9-12, 26-29 and 38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

***Response to Arguments***

1. Applicant's arguments filed October 3, 2005 have been fully considered but they are not persuasive.

After further consideration, examiner respectfully disagrees with the applicant's argument. Examiner would like to specifically point out to figure 21b where the catheter tip apparatus comprises of elongated housing rotatably supported on a flexible catheter sheath with rotating blades 312, which are longitudinally spaced apart from one another and optical delivery fiber 316 adjacent to the reflective surface of 312. The rotating blades direct the focusing and light illumination as well as receiving the reflected light.

In regards to claims 20 and 33, the arrangement of the reflective blade or mirrors is axially symmetrical to the longitudinal direction of the catheter. In addition, the argument that the sheath being transparent is inherent in the Boppart et al since the light or optical transmission and reception requires optically transparent window as shown in figure 8.

In regards to claims 39 and 41, Boppart et al illustrate in figure 21b where reflective surfaces or mirrors 312 are in communication with imaging module with focusing element 320 where the illumination direction is directed with lens, through reflective surface. Therefore, all claimed limitations argued by the applicant are anticipated in Boppart et al.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 20, 24, 25, 33, 39-41, and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by *Boppart et al* (US 6,485,413).

Boppart et al anticipate all claimed features in claims 1-3, 20, 24, 25, 33, 39-41, and 44.

**Claims 1, 20, 24, 25, 33, 39-41, and 44:** Boppart et al disclose a method and apparatus to detect a structure beneath a wall of a body lumen or cavity using a catheter comprising an elongated housing rotatably supported on a catheter sheath with the housing supporting a first and second reflective surfaces with first reflective surface is coupled to delivery fiber and second reflective surface is coupled to collection fiber (col. 2, lines 40-49; col. 2, lines 62-65; col. 4, lines 39-64; col. 7, lines 9-41). Although, the reflective surfaces are not spaced apart, however, they are functionally equivalent to two independent reflective surfaces.

**Claims 2 and 3:** Boppart et al illustrate in figure 8b where the reflective surface may be a rotating prism that redirects the beam.

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4-8, 13-19, 21-23, 30-32, 34-37, 42, 43, and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Boppart et al* as applied to claims 1, 2, 20, 33, 39, and 41 above, and further in view of *Winston* (US 5,916,210).

Boppart et al substantially disclose all claimed features in claims 4-8, 13-19, 21-23, 30-32, 34-37, 42, 43, and 46-48. However, Boppart et al do not specifically disclose the following features in which Winston's teaching supplements detailed structure of a similar optical coherent tomography (OCT) system.

**Claims 4 and 5:** Winston discloses of slot having shoulder or fitting sleeve over the rotating shaft to guide and align the reflective surface and allow the catheter to be manipulated into the sheath (col. 4, lines 23-34).

**Claims 6-8, 34-37, 46, and 48:** Winston discloses of the catheter described above with the reflector fitting into a pocket like flange where the mirror reflector is fixedly attached to the pocket where the mirror or reflectors redirects the light beams (col. 5, line 65 – col.6, line 11).

**Claims 13-15 and 17:** Winston's catheter disclosure includes reflective surface being unitary, within the catheter housing described having proximal end and distal ends with energy collecting fiber and slot to align the reflective surface (col. 4, lines 24-57).

Claim 19: Winston's catheter includes reflective surface enclosed in a catheter tip (col. 5, lines 59-64).

**Claims 16, 18, 19, 21-23, and 43:** Winston shows in figures 4, 5, and 12a that the reflective surfaces are in non-parallel position with one being larger than the other and the reflective surface is curvilinear.

**Claims 30 and 47:** Winston discloses of optical fiber 30 being enclosed within the catheter housing.

**Claim 31:** Winston discloses that the light delivery fibers are diametrically opposed to the rotation axis to prevent from unbalancing and minimize eccentricity during rotation (col. 9, line 54 – col. 10, line 7).

**Claim 32:** The reflective surfaces operate independently; therefore the energy delivery is independent.

Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Winston to Boppart et al to improve the OCT imaging of inner walls of lumen.

***Allowable Subject Matter***

6. Claims 9-12, 26-29, and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739.

The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*LKJ*

December 19, 2005

*Eleni Mantis-Mercader*  
ELENI MANTIS-MERCADER  
PRIMARY EXAMINER